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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,779	09/24/2003	Jeffrey M. Gross	4002-3423/PC890.00	6416

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,779	GROSS, JEFFREY M.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 9-14,31-34,37 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,15-30,35,36,38,39,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/22/03;11/18/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of **Fusion Implant**: Species B (shape of pin is tapered), and **Number of bone pieces**: Species A (two bone pieces) in the reply filed on February 3, 2006 is acknowledged.

The traversal is on the ground(s) that (i) “the elements identified by the examiner are not mutually exclusive”, (ii) “the embodiments shown are a reasonable number for consideration”, and (iii) “the PTO has the burden of proof to provide evidence and a sufficient showing that claims in an application are unpatentable, or should otherwise be excluded from an application”. This is not found persuasive.

2. With regards to the species group “Fusion Implant”, the Examiner agrees with the Applicant that “tapered” or “angled obliquely” is not mutually exclusive. However, the presence (independent claims 1, 25, 28, 30, 34, 35, 36, 38, 39, 41, and 42) or lack/absence (independent claims 31, 37, and 40) of a pin is mutually exclusive, and claims drawn to a fusion implant lacking a pin will be withdrawn. With regards to Applicant’s other two arguments (listed above), the Examiner required an Election of Species, not a Restriction. As defined in MPEP 808.01(a), for an Election of Species “*it is not necessary to show a separate status in the art or separate classification*”. Also, that same section of the MPEP teaches that for a multiplicity of species requiring extensive and/or burdensome search, “*a requirement for an election of species should be made prior to a search*”. Furthermore, the Office Action state: “*should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit*

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on the record that this is the case". The requirement is still deemed proper and is therefore made FINAL.

3. Claims 9-14, 31-34, 37, and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 3, 2006.

Claim Objections

4. Claim 35 is objected to because of the following informality: please substitute "the portion of the pin" (see line 5) with --a portion of the pin--. Otherwise said limitation will lack antecedent basis. Appropriate correction is required.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

a. Therefore, "the second tapered portion tapering away from the second exterior surface toward the first exterior surface such that the second pin has a larger portion that is near the second exterior surface and a smaller portion that is near the first exterior surface" (see claim 5) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

b. Therefore, "the pin extends through the body from one exterior surface to another" (see claim 7) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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c. Therefore, “the pin is embedded within the body, such that it is surrounded on all sides by the body” (see claim 8 and claim 30) must be shown or the feature(s) canceled from the claim(s).

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-8, 15-30, 35, 36, 38, 39, 41, and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. **10/669,764**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a fusion implant comprising two bone pieces held together by a pin/member. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, 4, 5, 7, 18, 19, 25, 26, 38, and 41 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shimp et al. (US 6,855,167 B2).

Referring to Figures 1, 2, 4, 6, 7, 21-32, 26(c)-26(f), 35, and 99, Shimp et al. disclose a fusion implant comprising: (i) a body having first (e.g., sheets/planks 30, 214, 267, 466) and second (e.g., sheets/planks 32, 216, 269, 468) pieces of bone assembled together to form a construct having exterior surfaces (e.g., top surface 12, bottom surface 14, side surfaces 17, 19, and end surfaces 16, 18); and (ii) at least one pin (e.g., pins 90) projecting into the first and second body pieces to hold them together, the pin having a first end (e.g., end 91) and a second end (e.g., end 93), a portion of the pin tapering (see column 11, lines 66-67; column 13, lines 25-29 and lines 58-64) between the first and second ends. The pins are made from bone, metal, or polymer (see column 24, lines 24-35). The pins ends are flush with the outer surfaces of the fusion implant (see column 12, lines 21-39), or extend through the body from one exterior surface to another (see Figure 99). The pins ends might be chamfered (see column 11, lines 60-63; column 22, lines 16-24). The pins are obliquely disposed (see Figures 6, 7, 26(d), and 26(e)) in order to restrain/prevent separation or slippage of the sheets/planks (see column 19, line 53 to column 20, line 27; column 24, lines 48-65).

10. Claims 1, 2, 3, 7, 8, 15-19, 25, 30, 38, and 41 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyd (US 6,761,738 B1).

Referring to Figures 1-12 and 17-24, Boyd discloses a fusion implant comprising: (i) a body having first (e.g., sheet/plank 12) and second (e.g., sheet/plank 14) pieces of bone

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assembled together to form a construct having exterior surfaces (see Figure 2); and (ii) at least one pin (e.g., cross-members 16) projecting into the first and second body pieces to hold them together, the pin having a first end (end 36) and a second end (end 37), a portion of the pin tapering (see Figure 20) between the first and second ends. The implant further comprises an opening through the body communicating with adjacent bony structures (see Figures 3, 4, 6, 8-12, 17 and 19; see columns 7, 10, and 12-14). The pins are made from bone, metal, or polymer. The pins ends are flush with the outer surfaces of the fusion implant (see Figures 3-5 and 8), extend through the body from one exterior surface to another (see Figures 22 and 24), or are embedded within the body (see Figure 10).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3, 8, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp et al. (US 6,855,167 B2).

Shimp et al. disclose the invention as claimed (see 102(e) rejection above). Although Shimp et al. disclose the pins ends as flush with the outer surfaces of the fusion implant (see column 12, lines 21-39), or as extending through the body from one exterior surface to another (see Figure 99), Shimp et al. did not disclose expressly said pin as exposed at a first surface of the implant and stopping short of another surface of the implant. At the time the invention was

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made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have modified Shimp et al. pin(s) to be exposed at a first surface of the implant and stopping short of another surface of the implant because Applicants have not disclosed that exposing a pin's first end at a first surface of the implant and stopping the second end of said pin short of another surface of the implant provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well with a pin having both ends flush/exposed, extending through, embedded, or having one end exposed at a surface of the implant. Furthermore, the instant application discloses (see PG Pub at paragraph 0030) said variations in pin insertion as optional (i.e., no criticality).

13. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp et al. (US 6,855,167 B2) in view of Boyd (US 6,761,738 B1).

Shimp et al. disclose the invention as claimed (see 102(e) rejection above). Although Shimp et al. disclose the desirability of fusing/stabilizing adjacent vertebrae, they did not particularly disclose the body of the implant as comprising an opening communicating with the adjacent bone structures. However, this is well known in the art. For example, Boyd discloses a fusion implant comprising an opening through the body communicating with adjacent bony structures, which opening contains bone growth promoting substance in order to promote/accelerate bone ingrowth and attachment of said implant to said adjacent bone structures (see Figures 3, 4, 6, 8-12, 17 and 19; see columns 7, 10, and 12-14). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a fusion implant comprising an opening communicating

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with the adjacent bone structures, which opening contains bone growth promoting substance, as taught by Boyd, with the fusion implant of Shimp et al., in order to promote/accelerate bone ingrowth and attachment of said implant to said adjacent bone structures.

14. Claims 20, 28, 39, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp et al. (US 6,855,167 B2) in view of Ferree (US 6,494,883 B1).

Shimp et al. disclose the invention as claimed (see 102(e) rejection above). Shimp et al. does not disclose the pins as angling through the construct obliquely such that it is neither parallel nor perpendicular to any of the exterior surfaces. However, this is already known in the art. For example, Ferree teaches a fusion implant comprising connecting struts angled through the construct obliquely such that it is neither parallel nor perpendicular to any of the exterior surfaces (see Figures 13A and 14A) in order to help hold bone graft into position (see column 6, lines 35-54). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a fusion implant comprising connecting struts angled through the construct obliquely such that it is neither parallel nor perpendicular to any of the exterior surfaces, as taught by Ferree, with the fusion implant of Shimp et al., in order to help hold bone graft into position.

15. Claims 21-24, 27, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp et al. (US 6,855,167 B2) in view of Foley et al. (US PG Pub No 2002/0107572 A1).

Shimp et al. disclose the invention as claimed (see 102(e) rejection above). Shimp et al. does not disclose the use of a fixation device with their fusion implant. However, this is well known in the art. For example, Foley et al. teach a fusion implant (Figures 1 and 2: implant 10) comprising a fixation device (plate 15) in order to substantially prevent movement of bony

structures adjacent the fusion implant (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a fusion implant comprising a fixation device, as taught by Foley et al., with the fusion implant of Shimp et al., in order to substantially prevent movement of bony structures adjacent the fusion implant.

16. Claims 29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimp et al. (US 6,855,167 B2), as modified by Ferree (US 6,494,883 B1), and further in view of Foley et al. (US PG Pub No 2002/0107572 A1).

Shimp et al., as modified by Ferree (US 6,494,883 B1), disclose the invention as claimed in claims 29 and 36 except for disclosing the use of a fixation device with their fusion implant. However, this is well known in the art. For example, Foley et al. teach a fusion implant (Figures 1 and 2: implant 10) comprising a fixation device (plate 15) in order to substantially prevent movement of bony structures adjacent the fusion implant (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a fusion implant comprising a fixation device, as taught by Foley et al., with the fusion implant of Shimp et al. (as modified by Ferree), in order to substantially prevent movement of bony structures adjacent the fusion implant.

Conclusion

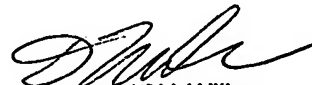
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

May 4, 2006

A large, stylized handwritten signature in black ink, consisting of a large 'J' and 'B' intertwined.A handwritten signature in black ink, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner